

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MATTHEW GRESS and KYLE MCNEIL,)	
Derivatively on Behalf of ACER)	C.A. No: 1:19-cv-01505-MN
THERAPEUTICS INC.,)	
)	
Plaintiffs,)	
)	
vs.)	
)	DEMAND FOR JURY TRIAL
)	
STEVE ASELAGE, CHRIS SCHELLING,)	
MICHELLE GRIFFIN, JOHN M. DUNN,)	
JASON AMELLO, HARRY PALMIN,)	
HUBERT BIRNER, and LUC)	
MARENBERE,)	
)	
Defendants,)	
)	
and,)	
)	
)	
ACER THERAPEUTICS INC.,)	
)	
Nominal Defendant.)	

VERIFIED SHAREHOLDER AMENDED DERIVATIVE COMPLAINT

Plaintiffs, by and through their undersigned counsel, derivatively on behalf of Nominal Defendant Acer Therapeutics Inc. (“Acer” or the “Company”), submit this Verified Shareholder Amended Derivative Complaint (the “Complaint”). Plaintiffs’ allegations are based upon their personal knowledge as to themselves and their own acts, and upon information and belief, developed from the investigation and analysis by Plaintiffs’ counsel, including a review of publicly available information, including filings by Acer with the U.S. Securities and Exchange Commission (“SEC”), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

I. NATURE OF THE ACTION

1. This is a shareholder derivative action brought in the right, and for the benefit, of Acer against certain of its officers and directors seeking to remedy Defendants' breach of fiduciary duties, unjust enrichment, and violations of § 14(a) of the Securities Exchange Act of 1934 (the "Exchange Act") that occurred between September 25, 2017 to the present (the "Relevant Period") and have caused substantial harm to Acer.

2. As more fully described herein, Acer is a pharmaceutical company that has and is seeking to bring certain drugs to market. To date, Acer has brought no drugs to market and has not generated any revenues. The drug at the center of this litigation is Celiprolol, which Acer has and is branding under the name "EDSIVO".

3. During (and prior to) the Relevant Period, the Company sought approval from the Food and Drug Administration ("FDA") of EDSIVO for the treatment of a rare genetic disorder known as vascular Ehlers-Danlos Syndrome ("vEDS"). The Company's FDA approval effort was through the New Drug Application ("NDA") process with the FDA.

4. To date, Celiprolol has not been approved for any indication in the United States but has been approved for the treatment of hypertension in the European Union since 1984 and is available there as a low-cost generic drug.

5. Rather than conducting its own clinical trials for EDVISO in support of its NDA, Acer sought NDA approval from the FDA by relying on an older and under-powered study published in France in 2010 (the "Ong Trial", more fully discussed herein).

6. Also, during the Relevant Period and EDSIVO NDA process, and because it was not generating any revenue, Defendants caused the Company to conduct two public offerings, one in December 2017 and the second in August 2018, raising \$12.56 million and \$46 million,

respectively.

7. In support of these public offerings, Defendants caused the Company to file prospectus supplements and other public filings and press releases which misrepresented that the Company had an agreement with the FDA that further clinical development beyond the Ong Trial was not needed or not likely needed in support of the EDSIVO NDA.

8. Acer's representation that the FDA had agreed that no additional clinical development was needed for the EDSIVO NDA to be approved by the FDA was extremely important to shareholders.

9. During this time and even though Acer was not generating any revenues, Defendants approved excessive compensation for themselves and others.

10. On June 25, 2019, the truth began to emerge. On that date, Defendants caused the Company to publish a press release disclosing that the FDA had denied the Company's EDSIVO NDA and that “[t]he [Complete Response Letter] states that it will be necessary to conduct an adequate and well-controlled trial to determine whether Celiprolol reduces the risk of clinical events in patients with vEDS.”

11. On this news, the Company's stock price fell by \$15.16 per share, or nearly 79%, to close at \$4.12 per share on June 25, 2019.

12. Based on Acer's wrongful conduct as caused by Defendants (defined below) and alleged herein, a securities class action lawsuit was commenced entitled *Skiadas v. Acer Therapeutics Inc., et al.*, Case No.: 1:19-cv-06137 (S.D.N.Y.) (the “Securities Class Action”).

II. JURISDICTION AND VENUE

13. Pursuant to 28 U.S.C. § 1331 and section 27 of the Exchange Act, this Court has jurisdiction over the claims asserted herein for violations of sections 14(a) of the Exchange Act

and SEC Rule 14a-9 promulgated thereunder. This Court has supplemental jurisdiction over the remaining claims under 28 U.S.C. § 1367.

14. Further, Diversity jurisdiction is conferred by 28 U.S.C. § 1332. Plaintiffs and the Defendants are citizens of different states and the amount in controversy exceeds the sum of value of \$75,000, exclusive of interest and costs.

15. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

16. Venue is proper in this Court in accordance with 28 U.S.C. §1391 because: (i) one or more of the defendants either resides in or maintains executive offices in this District; (ii) a substantial portion of the transactions and wrongs complained of herein, including Defendants primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to Acer, occurred in this District; and (iii) Defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

III. PARTIES

A. Plaintiffs

17. *Plaintiff Kyle McNeil* (“Plaintiff McNeil”) is, and was at relevant times, a shareholder of Acer. Plaintiff McNeil has continuously held Acer common stock since October 3, 2017. Plaintiff McNeil will fairly and adequately represent the interests of the shareholders in enforcing the rights of the corporation. Plaintiff McNeil is a citizen of the State of Florida

18. ***Plaintiff Matthew Gress*** (“Plaintiff Gress”) is, and was at relevant times, a shareholder of Acer. Plaintiff Gress has continuously held Acer common stock since June 18, 2019. Plaintiff Gress will fairly and adequately represent the interests of the shareholders in enforcing the rights of the corporation. Plaintiff Gress is a citizen of the State of Nevada.

B. Nominal Defendant

19. Nominal Defendant Acer is a Delaware corporation with its principal executive offices located at One Gateway Center, Suite 351, 300 Washington Street, Newton, Massachusetts. Nominal Defendant Acer is a citizen of the State of Delaware or the State of Massachusetts. Acer’s stock trades on NASDAQ under the ticker symbol “ACER.”

C. Director Defendants

20. ***Defendant Steve Aselage*** (“Aselage”) has served as the Chairman of the Board of Directors (“Board”) of the Company since the completion of the Opexa Therapeutics, Inc. merger (the “Opexa Merger”) on September 19, 2017. Defendant Aselage has been the Chair of the Compensation Committee and a member of the Nominating and Governance Committee since September 19, 2017. From 2017 through 2019, Defendant Aselage received compensation from the Company in the amount of \$303,765, consisting of fees earned or paid in cash and option awards. Defendant Aselage is a citizen of the State of California. The following is a summary of Defendant Aselage’s compensation:

Director	Compensation	2017	2018	2019
Steve Aselage	Fees Earned or Paid in Cash	\$18,438.00	\$73,500.00	\$73,750.00
	Option Awards	\$52,735.00	\$0.00	\$85,342.00
	All Other Compensation		\$0.00	\$0.00
	Total	\$71,173.00	\$73,500.00	\$159,092.00

21. ***Defendant Chris Schelling*** (“Schelling”) founded Private Acer in December 2013 and served as a director from that time until the Opexa Merger. From December 2013 to February

2016, he served as Private Acer's Chief Operating Officer ("COO"), and from February 2016 until the Opexa Merger, he served as Private Acer's President and Chief Executive Officer ("CEO"). Defendant Schelling has served as a director and as the Company's President and CEO since the completion of the Opexa Merger on September 19, 2017. From 2017 through 2019, Defendant Schelling received compensation from the Company in the amount of \$2,602,669, consisting of salary, bonus, and option awards. Defendant Schelling is a citizen of the State of Oregon. The following is a summary of Defendant Schelling's compensation:

Director	Compensation	2017	2018	2019
Chris Schelling	Salary	\$116,667.00	\$400,000.00	\$436,000.00
	Bonus	\$0.00	\$150,000.00	
	Option Awards	\$468,791.00	\$0.00	\$1,031,211.00
	All Other Compensation	\$0.00	\$0.00	
	Total	\$585,458.00	\$550,000.00	\$1,467,211.00

22. **Defendant Michelle Griffin** ("Griffin") has served as a director of the Company since the completion of the Opexa Merger on September 19, 2017. Defendant Griffin has served as the Chair of the Audit Committee and has been a member of the Compensation Committee since September 19, 2017. From 2017 through 2019, Defendant Griffin received compensation from the Company in the amount of \$286,856, consisting of fees earned or paid in cash and option awards. Defendant Griffin is a citizen of the State of Washington. The following is a summary of Defendant Griffin's compensation:

Director	Compensation	2017	2018	2019
Michelle Griffin	Fees Earned or Paid in Cash	\$13,750.00	\$55,000.00	\$55,000.00
	Option Awards	\$77,764.00	\$0.00	\$85,342.00
	All Other Compensation	\$0.00	\$0.00	\$0.00
	Total	\$91,514.00	\$55,000.00	\$140,342.00

23. **Defendant John M. Dunn** ("Dunn") has served as a director of the Company since the completion of the Opexa Merger on September 19, 2017. Defendant Dunn has served as a

member of the Audit Committee and Chair of the Nominating and Governance Committee since September 19, 2107. Defendant Dunn has served as a consultant and/or senior advisor to TVM Capital, an independent affiliation of international private equity and venture capital firms, since at least 2017 (“TVM”). TVM owns 26.5% of all the outstanding shares of Acer stock. From 2017 through 2019, Defendant Griffin received compensation from the Company in the amount of \$250,577, consisting of fees earned or paid in cash and option awards. Defendant Dunn is a citizen of the State of California. The following is a summary of Defendant Dunn’s compensation:

Director	Compensation	2017	2018	2019
John M. Dunn	Fees Earned or Paid in Cash	\$12,500.00	\$50,000.00	\$50,000.00
	Option Awards	\$52,735.00	\$0.00	\$85,342.00
	All Other Compensation	\$0.00	\$0.00	\$0.00
	Total	\$65,235.00	\$50,000.00	\$135,342.00

24. ***Defendant Jason Amello*** (“Amello”) has served as a director since the completion of the Opexa Merger on September 19, 2017. Defendant Amello has been a member of the Audit Committee since September 19, 2017. From 2017 through 2019, Defendant Amello received compensation from the Company in the amount of \$260,749, consisting of fees earned or paid in cash and option awards. Defendant Amello is a citizen of the State of Massachusetts. The following is a summary of Defendant Amello’s compensation:

Director	Compensation	2017	2018	2019
Jason Amello	Fees Earned or Paid in Cash	\$10,625.00	\$42,500.00	\$42,500.00
	Option Awards	\$77,764.00	\$0.00	\$85,342.00
	All Other Compensation	\$0.00	\$0.00	\$0.00
	Total	\$88,389.00	\$44,518.00	\$127,842.00

25. Defendants Aselage, Schelling, Griffin, Dunn and Amello are herein referred to as the “Director Defendants.”

D. Former Director Defendants

26. Defendant Hubert Birner (“Birner”) served as a director of the Company since the

completion of the Opexa Merger on September 19, 2017 until May 17, 2019. From April 2017 until the Opexa Merger, Defendant Birner served as a member of Private Acer's board of directors. Since 2000, Defendant Birner has served in a variety of roles for TVM Capital, an independent affiliation of international private equity and venture capital firms, where he currently serves as the Managing Partner of TVM Capital and TVM Life Science Management. Defendant Birner is a member of the investment committee of TVM VII GP, which has voting and investment power with respect to these shares and may be deemed to beneficially own such shares. Defendant Birner did not stand for reelection to the Board at Acer's May 17, 2019 Annual Meeting. Defendant Birner is a citizen of the country of Germany.

27. Defendant Luc Marengere ("Marengere") served as a director of the Company from September 19, 2017 until May 17, 2019. Defendant Marengere serves as Managing Partner of TVM Life Science Venture VII, L.P., which he joined in March 2012. Defendant Marengere is a member of the investment committee of TVM VII GP, which has voting and investment power with respect to these shares and may be deemed to beneficially own such shares. Defendant Marengere did not stand for reelection to the Board at Acer's May 17, 2019 Annual Meeting. Defendant Marengere is, upon information and belief, a citizen of the country of Germany.

28. Defendants Birner and Marengere are referred to as the "Former Director Defendants."

E. Officer Defendant

29. ***Defendant Harry Palmin*** ("Palmin") has served as the Company's Chief Financial Officer ("CFO") since the completion of the Opexa Merger in September 2017 and has also served as the Company's Chief Operating Officer since September 1, 2018. Defendant Palmin served as Private Acer's acting CFO since February 2016. Prior to that, Defendant Palmin served as the

President, CEO, and a Director of Private Acer from its founding in December 2013 until February 2016. From 2017 through 2019, Defendant Palmin received compensation from the Company in the amount of \$1,967,009, consisting of salary, bonus, and option awards. Defendant Palmin has served as the Company's CFO at all relevant times. Defendant Palmin is a citizen of the State of Massachusetts. The following is a summary of Defendant Palmin's compensation:

	Compensation	2017	2018	2019
Harry Palmin	Salary	\$99,167.00	\$340,000.00	\$382,400.00
	Bonus	\$0.00	\$89,250.00	\$0.00
	Option Awards	\$594,151.00	\$0.00	\$462,041.00
	All Other Compensation	\$0.00	\$0.00	\$0.00
	Total	\$693,318.00	\$429,250.00	\$844,441.00

30. The Director Defendants, the Former Director Defendants and Defendant Palmin are collectively referred to herein as the "Defendants."

IV. DUTIES OF DEFENDANTS

31. By reason of their positions as officers and/or directors of the Company, and because of their ability to control the business and corporate affairs of Acer, Defendants owed its investors the fiduciary obligations of trust, loyalty, and good faith. The obligations required Defendants to use their utmost abilities to control and manage Acer in an honest and lawful manner. Defendants were and are required to act in furtherance of the best interests of Acer and its investors.

32. Each defendant of the Company owes to Acer and its investors the fiduciary duty to exercise loyalty, good faith, and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets. In addition, as officers and/or directors of a publicly held company, Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's operations, finances, and financial condition, as well as present and future business prospects, so that the market price of the Company's stock would be

based on truthful and accurate information.

33. To discharge their duties, the officers and directors of Acer were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the affairs of the Company. By virtue of such duties, the officers and directors of Acer were required to, among other things:

- (a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;
- (b) conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
- (c) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;
- (d) remain informed as to how Acer conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;
- (e) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state, and local laws, and rules and regulations; and

(f) ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.

V. THE COMPANY'S CORPORATE GOVERNANCE

34. Each Defendant, by virtue of his position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets.

35. The conduct of Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Acer, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that Defendants were aware, or should have been aware, posed a risk of serious injury to the Company.

VI. WHISTLEBLOWER PROTECTIONS AND CODE OF ETHICS

36. Acer maintains a Whistleblower Protections and Code of Ethics policy (“Code of Ethics”). The Code of Ethics states:

The Company is committed to operating its business with honesty and integrity. To promote compliance with all applicable laws, rules and regulations, the Board of Directors has adopted a Code of Ethics that reiterates the standards of conduct and ethical behavior that we have always expected of our directors, officers and employees (collectively, “Representatives” and individually, a “Representative”).

37. The Code of Ethics also provides that it was “. . . designed to deter wrongdoing and to promote:”

- honest and ethical conduct, including the ethical handling of actual and apparent conflicts of interest between personal and professional relationships
- full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company files with, or submits to, the SEC and in other public communications made by the Company;
- compliance with applicable governmental laws, rules and regulations;
- the prompt internal reporting to an appropriate person or persons identified

- in the Code of violations of the Code; and
- accountability for adherence to the Code.

38. The Code of Ethics further provides:

I. Standards of Conduct

A. *Honest and Candid Conduct*

Representatives are expected to act and perform their duties ethically and honestly with the utmost integrity. Honest conduct is considered to be conduct that is free from fraud or deception. Ethical conduct is considered to be conduct conforming to accepted professional standards of conduct....

* * *

C. *Accuracy of Financial Reports and Other Public Communications*

The Company, as a public company, is subject to various securities laws, regulations and reporting obligations. Both federal law and our policies require the disclosure of accurate and complete information regarding the Company's business, financial condition and results of operations which may be filed with, or submitted to, the SEC and other regulators or disseminated publicly. Inaccurate, incomplete or untimely reporting will not be tolerated and can severely damage the Company and result in legal liability.

Senior Financial Officers are responsible for ensuring that the disclosure in the Company's periodic reports is full, fair, accurate, timely and understandable. In doing so, Senior Financial Officers shall take such action as is reasonably appropriate to (i) establish and comply with disclosure controls and procedures and accounting and financial controls that are designed to ensure that material information relating to the Company is made known to them, (ii) confirm that the Company's periodic reports comply with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and (iii) ensure that information contained in the Company's periodic reports fairly presents in all material respects the financial condition and results of operations of the Company.

D. *Compliance with Laws and Regulations*

It is the Company's policy to comply with all applicable laws, rules, and regulations. It is the personal responsibility of each Representative to adhere to the standards and restrictions imposed by those laws, rules, and regulations. In performing his or her duties, each Representative will endeavor to comply, and take appropriate action within his or her areas of responsibility to cause the Company to comply, with applicable governmental laws, rules, and regulations.

II. Compliance Procedures

A. Monitoring Compliance and Disciplinary Action

The Company's management, under the supervision of its Board of Directors or a committee thereof, or, in the case of accounting, internal accounting controls or auditing matters, the Audit Committee, shall take reasonable steps from time to time to (i) monitor compliance with the Code, including the establishment of monitoring systems that are reasonably designed to investigate and detect conduct in violation of the Code, and (ii) when appropriate, impose and enforce appropriate disciplinary measures for violations of the Code.

Disciplinary measures for violations of the Code may include, but are not limited to, oral or written reprimands, warnings, counseling, probation or suspension with or without pay, demotions, reductions in salary, termination of employment or service and restitution, disciplinary action, including termination.

Management of the Company shall periodically report to the Board of Directors or a committee thereof on these compliance efforts including, without limitation, periodic reporting of alleged violations of the Code and the actions taken with respect to any such violation.

B. Reporting Illegal or Unethical Behavior

Representatives are required to act proactively by asking questions, seeking guidance and reporting suspected violations of the Code and other policies and procedures of the Company, as well as any violation or suspected violation of applicable law, rule or regulation arising in the conduct of the Company's business or occurring on the Company's property. If any Representative believes that actions have taken place, may be taking place, or may be about to take place that violate or would violate the Code, he or she is obligated to bring the matter to the attention of the Company. The best starting point for a Representative seeking advice on ethics-related issues or reporting potential violations of the Code will usually be his or her supervisor. However, if the conduct in question involves his or her supervisor, if the Representative has reported the conduct in question to his or her supervisor and does not believe that he or she has dealt with it properly, or if the Representative does not feel that he or she can discuss the matter with his or her supervisor, the Representative should raise the matter with the Chief Legal Officer. Reports of allegations of improper conduct are encouraged to be made in writing so as to assure a clear understanding of the issues but may be made orally. You can also submit a report through our third-party hotline service, who will provide copies to our Chief Legal Officer and Chief Financial Officer...

VII. THE COMPANY'S AUDIT COMMITTEE CHARTER

39. The Audit Committee is charged with the following duties and provides in relevant

part:

IV. Duties and Powers of the Committee

To carry out its purposes, the Committee shall have the following duties and powers:

1. with respect to the independent auditors,
 - (i) to directly appoint, retain, compensate, evaluate, and terminate the independent auditors, including having the sole authority to approve all audit engagement fees and terms, provided that the auditor appointment shall be subject to stockholder approval;
 - (ii) to pre-approve, or to adopt appropriate procedures to pre-approve, all audit and non-audit services to be provided by the independent auditors;
 - (iii) to review and discuss the annual written statement from the independent auditors delineating all of the independent auditors' relationships with the Company (as required by the Public Company Accounting Oversight Board regarding the independent auditors' communications with an audit committee concerning independence) and, based on such review, assess the independence of the auditors;
 - (iv) to discuss with the independent auditors in connection with any audit all critical accounting policies and practices used, all alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, ramifications of the use of such alternative disclosures and treatments, and the treatment preferred by the independent auditors, and any material written communications between the independent auditors and management, such as any "management letter" or schedule of unadjusted differences and management's responses thereto;
 - (v) to discuss with management and the independent auditors the timing and process for implementing the rotation of the lead audit partner, the concurring partner and any other active audit engagement team partner;
 - (vi) to instruct the independent auditors that the independent auditors are ultimately accountable to the Committee, as representatives of the stockholders; and
 - (vii) to establish guidelines for the hiring of employees and former

employees of the independent auditors;

2. with respect to financial reporting principles and policies and internal controls and procedures,

(i) to advise management and the independent auditors that they are expected to provide to the Committee a timely analysis of significant financial reporting issues and practices;

(ii) to consider any reports or communications (and management's responses thereto) submitted to the Committee by the independent auditors, including reports and communications related to:

- deficiencies noted in the audit in the design or operation of internal controls;
- consideration of fraud in a financial statement audit;
- detection of illegal acts;
- any restriction on audit scope;
- significant accounting policies;
- management judgments and accounting estimates;
- any accounting adjustments arising from the audit that were noted or proposed by the auditors but were passed (as immaterial or otherwise);
- disagreements with management;
- difficulties encountered with management in performing the audit;
- the independent auditors' judgments about the quality of the entity's accounting principles; and
- reviews of interim financial information conducted by the independent auditors;

(iii) to meet with management and the independent auditors:

- to review and discuss the annual audited financial statements and quarterly financial statements, including the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations";
- to discuss any significant matters arising from any audit, including any audit problems or difficulties, whether raised by management or the independent auditors, relating to the Company's financial statements;
- to discuss any difficulties the independent auditors encountered in the course of the audit, including any restrictions on their activities or access to requested information and any significant disagreements with

- management;
- to review the form of opinion the independent auditors propose to render to the Board and stockholders; and
- to discuss, as appropriate: (a) any major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles, and major issues as to the adequacy of the Company's disclosure controls and procedures and internal control over financial reporting, and any special audit steps adopted in light of material control deficiencies; (b) analyses prepared by management and/or the independent auditors setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative GAAP methods on the financial statements; and (c) the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on the financial statements of the Company;

(iv) to discuss with management the Company's major financial risk exposures and the steps management has taken to monitor and control such exposures, including the Company's policies with respect to financial risk assessment and financial risk management;

(v) to inquire of and review any disclosures made to the Committee by the Company's chief executive officer and chief financial officer (or persons performing such functions) during their certification process for the Company's Form 10-K and Forms 10-Q as to the existence of any significant deficiencies or material weaknesses in the design or operation of internal controls that could adversely affect the Company's ability to record, process, summarize and report financial data, and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls;

(vi) to discuss with the Company's general counsel (or person or entity performing such function) any significant legal, compliance or regulatory matters that may have a material effect on the financial statements or the Company's business, financial statements or compliance policies, including material notices to or inquiries received from governmental agencies;

(vii) to discuss and review the type and presentation of information to be included in earnings press releases;

(viii) to establish procedures for the receipt, retention and treatment of

complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and for the confidential, anonymous submission by Company employees of concerns regarding questionable accounting or auditing matters; and

- (ix) to review and approve where appropriate any proposed “related person transactions” which may be required to be disclosed by the Company (pursuant to Item 404 of Regulation S-K), based on all relevant facts and circumstances reasonably available to the Committee (including, but not limited to: the nature of the related person’s interest in the transaction; the material terms of the transaction, including, without limitation, the amount and type of transaction; the importance of the transaction to the related person; the importance of the transaction to the Company; whether the transaction would impair the judgment of a director or executive officer to act in the best interest of the Company; and any other matters the Committee deems appropriate), where approval is given by the Committee only for those transactions it determines are fair to and in the best interests of the Company, taking into account all factors deemed relevant by the Committee;

3. with respect to reporting and recommendations,

- (i) to recommend to the Board, based on its review and discussions with management and the independent auditors, whether the Company’s audited financial statements should be included in the Company’s annual report on Form 10-K;
- (ii) to prepare any report or other disclosures, including any recommendation of the Committee, required by the rules of the SEC to be included in the Company’s annual proxy statement;
- (iii) to review and reassess the adequacy of this Charter at least annually and recommend any changes to the full Board;
- (iv) to prepare and review with the Board an annual performance evaluation of the Committee, which evaluation shall compare the performance of the Committee with the requirements of this Charter;
- (v) to report its activities to the full Board on a regular basis and to make such recommendations with respect to the above and other matters as the Committee may deem necessary or appropriate;
- (vi) in the case of matters concerning accounting, internal controls or auditing, to monitor compliance with the Company’s Code of Ethics

and when appropriate, impose and enforce appropriate disciplinary measures for violations of the Code; and

- (vii) to review any proposed waiver of the Code and make a recommendation to the Board with respect to the disposition of any proposed waiver.

VIII. BACKGROUND

A. The Company's Background

40. Acer is a pharmaceutical company that purportedly focuses on the acquisition, development, and commercialization of therapies for serious rare and life-threatening diseases. The Company's pipeline includes, *inter alia*, EDSIVO (its branded name for Celiprolol) for the treatment of vascular Ehlers-Danlos syndrome ("vEDS") in patients with a confirmed type III collagen mutation.

41. Acer was formed in 2013 as a private company by Defendant Schelling ("Private Acer").

42. On September 19, 2017, Acer published a press release ("09/19/17 Press Release") announcing that Private Acer had closed a merger with Opexa Therapeutics, Inc. ("Opexa"), a publicly-traded Texas pharmaceutical corporation, whereby Private Acer survived as a wholly-owned subsidiary of Opexa. Following the Opexa Merger, Opexa changed its name to Acer Therapeutics Inc. and Private Acer's management took control of the combined company. Immediately prior to the Opexa Merger, Opexa's board of directors and Neil K. Warma ("Warma"), Opexa's then-President, CEO, Acting CFO, and Secretary, resigned. Also immediately following the Opexa Merger, the Company's new Board was comprised of Defendants Schelling, Amello, Aselage, Griffin, Dunn, Birner and Marengere.

43. As stated in the 09/19/17 Press Release, "[f]ollowing the completion of the [Opexa] Merger, the business conducted by [Opexa] became primarily the business conducted by Private

Acer, which is a pharmaceutical company that acquires, develops and intends to commercialize therapies for patients with serious rare diseases with critical unmet medical need.”

44. On September 21, 2017, the Company began trading on the NASDAQ under the ticker symbol “ACER”.

45. On May 15, 2018, the Company changed its state of incorporation from Texas to Delaware. Following its reincorporation, the Company eliminated its holding company structure by merging the wholly owned subsidiary Private Acer with and into the Company.

46. Since going public, the Company has had at most, three clinical pipeline products it describes as EDSIVO (for the treatment of vEDS), ACER-001 (for the treatment of urea cycle disorders, or UCD, and Maple Syrup Urine Disease, or MSUD), and osanetant (for the treatment of various neuroendocrine disorders). The Company describes EDSIVO as “Our most advanced product candidate”.

47. To date, the Company has not generated any revenue. As stated in its annual report for the fiscal year ended December 31, 2019 and filed on Form 10-K with the SEC on March 18, 2020 (the “2019 Form 10-K”):

We have not generated any revenue to date Our net loss for the years ended December 31, 2019 and 2018 was \$29.4 million and \$21.3 million, respectively. As of December 31, 2019, we had an accumulated deficit of \$76.3 million.

* * *

Our ability to generate product revenue depends upon our ability to successfully identify, develop and commercialize these product candidates [EDSIVO, ACER-001, and osanetant] or other product candidates that we may develop, in-license or acquire in the future.

48. As stated in its 2019 Form 10-K, the Company has spent approximately \$42.3 million in research and development expenses through December 31, 2019. Of that amount, approximately \$31.1 million was directly related to EDSIVO, while only approximately \$9.8

million was directly related to ACER-001.

49. Because of the Company's large R&D investment in EDSIVO, Defendants have informed investors of the importance of obtaining FDA approval. As stated in the 2019 Form 10-K:

Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates in the U.S. without first obtaining approval from the FDA to market each product candidate.

50. In order for the Company to bring EDSIVO to market and generate revenue, it needs to complete clinical trials, submit a NDA with the FDA, and obtain approval from the FDA.

B. NDA Process

51. The FDA website¹ states in relevant part:

Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.

¹

<https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

52. In its 2019 Form 10-K, the Company describes the NDA approval process in relevant part:

The FDA is required to conduct a preliminary review of an NDA within the first 60 days after submission, before accepting it for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may accept the NDA for filing, potentially refuse to file the NDA due to deficiencies but work with the applicant to rectify the deficiencies (in which case the NDA is filed upon resolution of the deficiencies) or refuse to file the NDA. The FDA must notify the applicant of a refusal to file a decision within 60 days after the original receipt date of the application Once an NDA is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act (“PDUFA”) and the FDA’s commitments under the current PDUFA Reauthorization Act, the FDA has a goal of reviewing and acting on 90% of standard non-priority NDA applications within six or ten months from the filing date of the NDA.

The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for its intended use and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product’s continued safety, quality and purity. The FDA is required to refer an application for a novel drug or class to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation in response to specific questions raised by the FDA, which may include whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

* * *

After the FDA evaluates the NDA and conducts its inspections, it may issue an approval letter or a Complete Response Letter [CRL]. An approval letter authorizes commercial marketing of the drug subject to specific prescribing information for specific indication(s) and, if applicable, specific post-approval requirements. A Complete Response Letter indicates that the review cycle of the application is complete but the application is not ready for approval. After receiving a Complete Response Letter, the applicant must decide within twelve months (subject to extension), if it plans to resubmit the NDA addressing the deficiencies identified by the FDA in the Complete Response Letter, withdraw the NDA, or request an opportunity for a hearing to challenge the FDA’s determination. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the data in the NDA

does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret this data differently than we interpret the data.

**PRIOR EXPERIENCE OF DEFENDANTS
WITH CLINICAL TRIALS, NDA FILINGS AND THE FDA**

53. The Director Defendants have extensive experience in the pharmaceutical industry, NDAs, and clinical trials as described below.

54. Defendant Amello served as Senior Vice President, CFO and Treasurer of Akebia Therapeutics, Inc. (“Akebia”), a Nasdaq-listed biopharmaceutical company. From May 2012 to May 2013, Defendant Amello served as Executive Vice President, CFO and Treasurer of ZIOPHARM Oncology, Inc. (“ZIOPHARM”), a biopharmaceutical company. From April 2000 to June 2011, Defendant Amello held various positions at Genzyme Corporation (“Genzyme”), a biotechnology company, most recently as Senior Vice President, Corporate Controller, and Chief Accounting Officer. By way of example, Akebia is a biopharmaceutical company focused on developing and commercializing novel therapeutics focusing on renal disease. Its leading drug candidate is Vadadustat which has gone through many clinical trials.

55. Defendant Aselage served as the Chairman of Private Acer’s board of directors from October 2015 until the Opexa Merger. Most recently, Defendant Aselage was President and CEO of Retrophin, Inc. (“Retrophin”), a Nasdaq-listed biopharmaceutical company, from November 2014 until his retirement in January 2019, and remains a member of its board of directors since October 2012. From May 2014 to November 2014, Defendant Aselage served as the COO and interim CEO of Retrophin. Prior to joining Retrophin, Defendant Aselage held a variety of roles at BioMarin Pharmaceutical Inc. (“BioMarin”), a Nasdaq-listed biotechnology company, as Executive Vice President and Chief Business Officer from December 2009 to September 2012 and Senior Vice President of Global Commercial Development from July 2005

to December 2009. Defendant Aselage earned a B.S. in biology from the University of Notre Dame. By way of example, Retrophin is a biopharmaceutical company focused on identifying, developing and delivering life-changing therapies to people living with rare diseases. It has several drugs presently available for sale (*e.g.*, Chenodal and Thiola) and several others in clinical developments (*e.g.*, Fosmetpantotenate (RE-024) and Sparsentan (RE-021), both of which are in Phase 3 clinical trials). On November 12, 2018, Retrophin announced the FDA's acceptance of its NDA filing for a new formulation of Thiola.

56. Defendant Dunn served as a member of Private Acer's board of directors from October 2015 until the Opexa Merger. From November 2014 to April 2019, Defendant Dunn served as General Counsel of Vital Therapies, Inc. ("Vital"), a Nasdaq-listed biotherapeutic company. Prior to joining Vital, Defendant Dunn was a consultant from February 2012 to November 2014, an Executive Vice President of Biogen Idec, Inc., now Biogen Inc. ("Biogen"), a biotechnology company, from November 2003 to January 2012, where he was the head of that Biogen's corporate venture group, and General Counsel of IDEC Pharmaceuticals ("IDEC") from 2002 until its merger with Biogen in November 2003. By way of example, Biogen is a global biopharmaceutical company focused on discovering, developing and delivering worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. Biogen has (and had while Defendant Dunn was employed there) multiple drugs available for sale and nearly twenty (20) drug candidates in various stages of development from preclinical through phase 3 clinical trials.

57. Defendant Griffin has served as the Principal of Pacific Biotechnology Consulting Group ("Pacific") since April 2013. Pacific is a firm providing consulting services to biotechnology companies. Prior to her time with Pacific, Defendant Griffin served as Executive

Vice President, Operations and CFO of OncoGenex Pharmaceuticals, Inc. (“OncoGenex”) from January 2011 to March 2013. Defendant Griffin has also served as a member of the board of directors and as Chair of the audit committee for Adaptive Biotechnologies Corporation since March 2019 and for HTG Molecular Diagnostics, Inc. since August 2018. Defendant Griffin previously served as a member of the board of directors and as Chair of the audit committee for (i) PhaseRx, Inc. from 2016 until its acquisition by Roivant Sciences GmbH in 2018; (ii) OncoGenex Pharmaceuticals, Inc. from 2008 to 2011; and (iii) Sonus Pharmaceuticals, Inc. (subsequently acquired by OncoGenex) from 2004 to 2008. During various periods from 1997 to 2011, Defendant Griffin served as CFO for Trubion Pharmaceuticals, Inc., Dendreon Corporation and Corixa Corporation. By way of example, during her time at OncoGenex that company was pursuing drug candidates through the clinical trial process.

58. Prior to founding Private Acer, Defendant Schelling served as Executive Director of Strategic Marketing at BioMarin Pharmaceutical Inc. (“BioMarin”), a Nasdaq-listed biotechnology company from May 2006 to October 2012. Defendant Schelling also founded Censa Pharmaceuticals Inc. (“Cesna”) in 2015 and currently serves as a director. Defendant Schelling has also served as a director at Cascade Prodrug, Inc. (“Cascade”) since June 2017. Defendant Schelling has also held roles at Abgenix, Inc., Cell Therapeutics, Inc., Stanford Research Institute Consulting and Organon. By way of example, and as described in its annual report for the fiscal year ended December 31, 2011, “BioMarin [] develops and commercializes innovative pharmaceuticals for serious diseases and medical conditions. We select product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market or offer a significant benefit over existing products.” During Defendant Schelling’s time at BioMarin, BioMarin was pursuing

various commercial products and major development programs which either completed the NDA process and were approved by the FDA or were in various stages of clinical trials.

59. Defendant Birner served as a member of Private Acer's board of directors from April 2017 until the Opexa Merger. Defendant Birner has also served as the Chairman of the boards of directors of Argos Therapeutics, Inc. ("Argos"), a Nasdaq-listed immuno-oncology company, and NOXXON Pharma N.V. ("NOXXON"), a EuroNext Growth Paris-listed biopharmaceutical company, and as a member of the board of directors of Proteon Therapeutics, Inc. ("Proteon"), a Nasdaq-listed biopharmaceutical company, as well as a number of privately held life science companies. Defendant Birner has also served as the Vice Chairman of Evotec AG ("Evotec"), a Frankfurt Stock Exchange-listed company focused on the discovery and development of small molecule drugs, from 2005 to 2013, and as a director of Probiodrug AG ("Probiogruug"), a Euronext Amsterdam-listed biopharmaceutical company from 2014 to 2015. Defendant Birner earned a Ph.D. in biochemistry from Ludwig-Maximilian University of Munich and an M.B.A. from Harvard Business School. By way of example, Proteon describes itself as "... a late-stage biopharmaceutical company focused on the development of novel, first-in-class pharmaceuticals to address the needs of patients with renal and vascular disease." During Defendant Birner's tenure there, Proteon's drug candidate vonapanitase had completed Phase 2 and Phase 3 clinical trials and had extensive interactions with the FDA regarding this drug.

60. Defendant Marengere served as a member of Private Acer's board of directors from April 2016 until the Opexa Merger. Defendant Marengere serves on the boards of directors of a number of privately held life science companies. From January 2015 to March 2017, he served on the board of directors of CoLucid Pharmaceuticals, Inc. ("CoLucid"), a Nasdaq-listed biopharmaceutical company. Defendant Marengere earned a Ph.D. from the University of

Toronto, an M.S. in endocrinology from Queen's University and a B.S. in biochemistry from the University of Ottawa. By way of example, while Defendant Marengere served on the board of CoLucid, it described itself as ". . . a Phase 3 clinical-stage biopharmaceutical company that is developing an innovative and proprietary small molecule for the acute treatment of migraine" and was responsible for various clinical trials, including for Lasmiditan.

IX. vEDS BACKGROUND AND THE COMPANY'S DRUG CANDIDATE, EDSIVO

A. vEDS

61. vEDS is a rare disease known to cause abnormal fragility in blood vessels, causing aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which are potentially life threatening. According to the Company, "[t]he median survival age of vEDS patients in the United States is 51 years, with arterial rupture being the most common cause of sudden death." vEDS is caused by changes or mutations in the gene called COL3A1 that tells the body how to make collagen III.

62. There are no drugs approved for the treatment of vEDS in the United States or internationally. Some beta-blocker class of drugs, which are generally used to treat high blood pressure, are prescribed off-label as part of management of vEDS. Celiprolol is one of the beta-blocker class of drugs which has not been approved for any indication in the United States but has been approved for the treatment of hypertension in the European Union since 1984. Celiprolol is available as a low-cost generic in the European Union and is the primary drug used to treat vEDS patients in several European countries, including France. Although Celiprolol is not approved by the FDA, patients can import it for personal use, including through online pharmacies.

63. On August 9, 2019, the Ehlers-Danlos Society published a "Consensus statement from The Ehlers-Danlos Society and professional members of the vEDS community." The Ehlers-

Danlos Society Consensus Statement states in relevant part:

There is not enough evidence to know for sure whether people with vEDS should take celiprolol or another medication to manage blood pressure to try to change the rate of arterial complications. Some medical centers with expertise in vEDS use celiprolol for their patients. Other medical centers with expertise in vEDS use other blood pressure medications. Since there is not one clear best option right now, people with vEDS should talk with their health care provider to create a plan based on their personal medical history.

64. On January 1, 2015, Private Acer published a press release announcing that the FDA granted it Orphan Drug Designation for its development of Celiprolol for the treatment of vEDS.

65. Orphan Drug Designation (also known as “Orphan Drug Exclusivity”) provides seven years of marketing exclusivity upon the approval of a drug intended to treat a rare condition. During that time, the FDA will not approve any other drug for the same indication unless it demonstrates clinical superiority. The purpose of Orphan Drug Exclusivity is to promote the development of drugs to treat rare diseases.

66. Private Acer and its successor, Acer, did not intend to conduct an additional clinical study of EDSIVO. Instead, the Company intended to rely on the Ong Trial (discussed below) and a Long-Term Observational Study (also discussed below).

B. The Ong Trial

67. On December 13, 2016, Private Acer issued a press release announcing that it had obtained exclusive rights to NDA-enabling clinical data from the French research hospital, Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou (“AP-HP”), for the use of Celiprolol in treating vEDS. Specifically, Private Acer had signed an agreement with AP-HP, which granted exclusive rights to access and use data from its trial commonly known as the “Ong Trial”. Private Acer announced it would use this data to support its NDA for Celiprolol

in the treatment of vEDS.

68. In 2004, AP-HP published data on vEDS patients. Based on AP-HP's research, investigators began assessing the preventive effect of Celiprolol for major cardiovascular events in patients suffering from vEDS "through a multicenter, prospective, randomized, open trial with blinded evaluation of clinical events" (the "Ong Trial"). The Ong Trial was composed of fifty-three (53) participants "randomized at eight centers in France and one center in Belgium." The Ong Trial's results were published on October 30, 2010.

69. In its 2019 Form 10-K, the Company described the Ong Trial in relevant part:

Fifty-three participants were enrolled in the Ong trial and randomized at eight centers in France and one center in Belgium. Patient ages ranged from 15 to 65 (with a mean age of 35), with a female-to-male ratio of 2-to-1. Patients were randomly assigned to a five-year intervention, receiving either celiprolol or no treatment, with important phenotype characteristics equally balanced between the celiprolol group and the control group. Celiprolol was administered twice daily to patients in the celiprolol group and the dosage was up-titrated every six months by 100 milligrams per day to a maximum of 400 milligrams per day. Patients assigned to the control group received the same attention as those assigned to the celiprolol group but did not receive celiprolol or any beta blocker. Thirty-three of the 53 patients participating in the study had proven mutations in the COL3A1 gene. Of those patients with proven mutations, demographic and arterial characteristics did not differ from those of the study population as a whole. The duration of follow-up was five years or until the first qualifying cardiac or arterial event. The primary endpoint was a composite of cardiac or arterial events (rupture or dissection, fatal or not) during follow-up. Secondary endpoints were gastrointestinal or uterine rupture. The study was ended early after a consensus decision of the safety monitoring board, the methodologist of AP-HP, and the principal investigator because significant differences were recorded between the treatment group and the control group after 64 months.... The hazard ratio ("HR") for event-free survival, was 0.36, (95% CI 0.15—0.88; p=0.040), meaning that with celiprolol the risk of having a cardiac or arterial event was reduced by 64% compared to control.

70. As discussed below, the Ong Trial was severely flawed, and because of these flaws its results were unreliable. The Ong Trial was flawed in the following respects:

- (a) the small size of its participant pool which made it underpowered;
- (b) more than one-third of the participants did not have a COL3A1 gene

mutation which was not good clinical practice;

(c) the COL3A1 gene mutation was not evenly distributed between the Celiprolol group of the study and the control group, which created bias in favor of the

group of patients taking Celiprolol versus the control group;

(d) 12 of the 25 patients in the Celiprolol arm did not have a proven COL3A1

mutation, and only 8 out of the 28 patients in the control group did not have the proven

genetic mutation; and

(e) the study was retrospective in nature which introduced selection bias.

71. Each of these flaws in the Ong Trial was a red flag to Defendants.

72. The Director Defendants, because of their prior experience in the biopharma industry working for companies which had conducted clinical trials as part of each company's NDA submissions, and had oversight of these clinical trials and the NDA process, knew or recklessly disregarded the red flags in the Ong Trial.

C. Long-Term Observational Study

73. On April 15, 2019, the American College of Cardiology published the results from its long-term observational study to determine the long-term outcomes associated with vascular Ehlers-Danlos Syndrome (vEDS) in the Journal of the American College of Cardiology ("JACC"). This observational study describes outcomes in 144 COL3A1-positive vEDS patients clinically monitored and treated at the French National Referral Center for Rare Vascular Diseases between the years 2000 and 2017. The methodology used was:

Patients referred to a large referral center with confirmed COL3A1 gene mutations consistent with vEDS were followed for up to 17 years. Patients were recommended to receive celiprolol (≤ 400 mg/day) in addition to usual care and annual follow-up. vEDS-related events and death were assessed for all patients.

74. On April 16, 2019, Defendants caused the Company to publish a press release

discussing this long-term observational study:

The authors concluded that in this large, long-term cohort study, vEDS patients had a higher survival rate than expected relative to the known natural history of the disease and a lower annual occurrence of arterial complications, and that celiprolol use was potentially associated with these significant improvements in clinical outcomes.

75. The April 16, 2019 press release also quoted Dr. William Andrews, Chief Medical Officer for the Company:

We are pleased to see this publication from the vEDS clinical investigator group in Paris which provides patients and physicians with a greater understanding of this chronic disease, including data suggesting a positive impact of celiprolol, which has a unique pharmacological profile

76. On May 14, 2019, Defendants caused the Company to issue a press release regarding its first quarter 2019 financial results. This press release quoted Defendant Schelling:

[I]n April 2019, we announced the publication of the Paris registry data in JACC that supplements the previously-reported safety and efficacy of celiprolol in vEDS patients with a confirmed type III collagen (COL3A1) mutation.

77. When issuing the April 16, 2019 and May 14, 2019 press releases, Defendants caused the Company to omit relevant information that dramatically impacts this “conclusion”. Namely, the study states:

It is difficult to formally assess this beneficial effect in the absence of a placebo-controlled prospective trial, because other confounders might have influenced this observation. In that regard, it can be argued that there is still no study that definitively proves that celiprolol affects mortality or vascular events.

D. The Company’s December 2017 and July 2018 Public Offerings Raise Much Needed Capital

78. Shortly after the completion of the Opexa Merger, the Company used its new status as a public company to raise money from investors in a secondary public offering of stock.

79. On December 11, 2017, Defendants caused the Company to file a Prospectus Supplement with the SEC. The purpose of this Prospectus Supplement was to raise capital to fund

the Company's efforts to bring EDSIVO to market. Defendants caused the Company to summarize the status of its drug candidate pipeline as follows:

Program / Indication	Novel MOA / Unique Characteristics	Phase 1	Phase 2	Phase 3	NDA	Market
EDSIVO™ (celiprolol)						
vEDS (COL3A1+)	Improves hemodynamic stability; decreases vascular resistance					
ACER-001 (reformulated sodium phenylbutyrate)						
UCD	Comparable to Buphenyl; taste-masked					
MSUD	Inhibition of BCKD kinase to increase BCAA metabolism					

80. This Prospectus Supplement also states in relevant part:

In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, ***the FDA agreed that additional clinical development is not needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS. [Emphasis added]

81. On December 27, 2017, Defendants caused the Company to file a Form 8-K with the SEC and publish a press release announcing that the Company received gross proceeds of \$12.56 million from the secondary offering.

82. On March 7, 2018, Defendants caused the Company to file its annual report for the year ending December 31, 2017 with the SEC ("2017 Form 10-K"). The 2017 Form 10-K was signed by all Defendants. Defendants continued to assure investors that the FDA would approve EDSIVO based on the Ong Trial:

In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS

In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and

manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.

We plan to have a pre-NDA meeting, which may consist of one or more consults, with the FDA in the second quarter of 2018. Subsequently, we expect to submit the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS at the end of the first half of 2018. [Emphasis added].

83. On July 31, 2018, Defendants caused the Company to file a Prospectus Supplement with the SEC. The purpose of this Prospectus Supplement was to raise additional capital to fund the Company's efforts to bring EDSIVO to market. Defendants caused the Company to summarize the status of its drug candidate pipeline as follows:

Program / Indication	Novel MOA / Unique Characteristics	Phase 1	Phase 2	Phase 3	NDA	Market
EDSIVO™ (celiprolol)						
vEDS (COL3A1+)	Improves hemodynamic stability; decreases vascular resistance					
ACER-001 (reformulated sodium phenylbutyrate)						
UCD	Comparable to Buphenyl; taste-masked					
MSUD	Inhibition of BCKD kinase to increase BCAA metabolism					

Key Regulatory Milestones

- NDA submission for EDSIVO™ (vEDS) expected early Q4 2018
- NDA submission for ACER-001 (UCD) anticipated late Q4 2019*

84. Defendants caused this Prospectus Supplement to state as follows:

In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not

likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS

In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.

In June 2018, we held a Type C meeting and a Type B (pre-NDA) meeting with the FDA. We expect to submit the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS early in the fourth quarter of 2018. We also intend to request priority review for EDSIVO™ which, if granted, could result in a Prescription Drug User Free Act (PDUFA) action date in the late second quarter 2019. Additionally, the manuscript for the Paris (AP-HP) vEDS patient registry data has been submitted and is currently under peer review, and if published, will be included in support of our NDA but is not rate-limiting to submission of the NDA. [Emphasis added].

85. On August 3, 2017, Defendants caused the Company to file a Form 8-K with the SEC and publish a press release announcing that the Company received gross proceeds of \$46 million from this offering.

X. ADDITIONAL BACKGROUND

86. On September 25, 2017, Defendants caused the Company to publish a press release entitled “Acer Therapeutics Reports Positive Results From Pivotal Clinical Trial of EDSIVO™ (Celiprolol) for Treatment of Vascular Ehlers-Danlos Syndrome.” This press release discussed the Ong Trial, describing it as its “retrospective source” and stated that it “. . . will use this pivotal clinical data to support a New Drug Application (NDA) regulatory filing in the U.S. in the first half of 2018.”

87. On April 9, 2018, Defendants caused the Company to file its Notice of Annual Meeting of Shareholders to be held on May 14, 2018 on Form DEF 14A with the SEC (the “2018

Proxy Statement”). Accompanying the 2018 Proxy Statement was the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the “2017 Form 10-K”). The 2018 Proxy Statement asked Plaintiffs and other Company shareholders to vote on: (1) election of directors; (2) approve Acer’s reincorporation in Delaware; and (3) approve the Acer 2018 Stock Incentive Plan. The Audit Committee report was included in the 2018 Proxy Statement. Neither the Audit Committee Report or the 2018 Proxy Statement mentioned EDVISO, vEDS, or disclosed any significant deficiencies or material weaknesses in the design or operation of internal controls that could adversely affect the Company’s ability to record, process, summarize and report financial data, and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company’s internal controls.

88. On December 26, 2018, Defendants caused the Company to announce that the FDA had accepted the Company’s NDA for EDSIVO for the treatment of vEDS in patients with a confirmed type III collagen mutation, as well as the FDA’s grant of priority review of the NDA and an assigned Prescription Drug User Fee Act (“PDUFA”) target action date of June 25, 2019.

89. Throughout the Relevant Period, Defendants caused the Company to make materially false and misleading statements regarding the Company’s business, operational and compliance policies. Specifically, Defendants caused the Company to make false and/or misleading statements and/or failed to disclose that: (1) the Company lacked sufficient data to support filing EDSIVO’s NDA with the FDA for the treatment of vEDS; (2) the Ong Trial was an inadequate and ill-controlled clinical study by FDA standards, and was comprised of an insufficiently small group size to support EDSIVO’s NDA; (3) consequently, the FDA would likely reject EDSIVO’s NDA; and (4) as a result, the Company’s public statements were materially false and misleading at all relevant times.

XI. MATERIALLY FALSE AND MISLEADING STATEMENTS

90. On September 25, 2017, Defendants caused the Company to issue a press release announcing *Positive Results From Pivotal Clinical Trial of EDSIVO* for the treatment of vEDS (the “September 2017 Press Release”). Despite the Ong Trial’s small group size of only fifty-three (53) participants, the September 2017 Press Release touted the Ong Trial as a comprehensive study with positive results that would support the Company’s NDA for EDSIVO:

Acer’s retrospective source verified analysis of the trial data, including the primary and secondary endpoints, confirmed the data from a previously published randomized controlled clinical study of celiprolol (1). Acer will use this pivotal clinical data to support a New Drug Application (NDA) regulatory filing in the U.S. in the first half of 2018.

* * *

The previously completed European study, published on October 30, 2010, in *The Lancet*, was stopped early having achieved statistical significance in its primary endpoints, with arterial dissection or rupture affecting 5 (20%) celiprolol patients and 14 (50%) subjects in the non-treated control group (hazard ratio [HR] 0.36; pvalue 0.04). The combined primary and secondary endpoints of intestinal or uterine rupture affected 6 (24%) celiprolol patients and 17 (61%) subjects in the non-treated control group (HR 0.31; p-value 0.01). The study was conducted in 53 patients, who were randomly assigned either a twice daily treatment of celiprolol or no treatment. Mean duration of follow-up was 47 months prior to trial halt.

91. The September 2017 Press Release also included a statement by Pierre Boutouyrie (“Boutouyrie”) M.D., Ph.D., co-director of the clinical pharmacology service at AP-HP, and Principal Investigator for the published Celiprolol study. Boutouyrie touted “nearly two decades” worth of data obtained on EDSIVO in vEDS patients and that the drug was the “standard of care” for vEDS patients in France. Mr. Boutouyrie stated:

We have studied celiprolol for nearly two decades in vEDS patients and this is the only drug to ever demonstrate a clinical benefit in this difficult to treat patient population in a randomized, controlled clinical study Having established celiprolol as the standard of care in France for vEDS patients, we are excited to collaborate with Acer to help bring celiprolol to U.S. patients who are suffering from this devastating, life-threatening disease.

92. Additionally, the September 2017 Press Release included a statement by the Company's Chief Medical Officer, Robert D. Steiner, M.D., who stressed that the Company had vetted the Ong Trial data, and that this data was a "critical element" of EDSIVO's NDA:

Our confirmation of the published celiprolol clinical data with an Acer-sponsored retrospective source verified analysis of the trial data represents a critical element of the clinical module in our NDA, which we are diligently building, along with current manufacturing, non-clinical and other components of the regulatory package.

93. Finally, the September 2017 Press Release included a statement by Defendant Schelling, who touted the Ong Trial as a "robust" clinical study with endpoints verified by the Company, which would "rapidly advance" EDSIVO's product development:

We continue to successfully rapidly advance our lead product candidate, EDSIVOTM, a potential life-saving therapy for patients with vEDS, towards an NDA filing, which we expect to accomplish in the first half of 2018 In addition to source verifying a definitive Event-Free Survival endpoint from a previously completed *robust clinical study*, modernizing manufacturing and assembling other components of the regulatory package, we are executing on a number of key medical affairs focused initiatives for vEDS patients. Specifically, we are setting up Centers of Excellence to optimize patient care, and intend to develop a prospective vEDS Patient Registry and provide integrated care support programs.

[Emphasis added].

94. The September 2017 press release was false and misleading because the Ong Trial was not a "robust clinical trial." In authorizing or otherwise supporting this press release, Defendants knew or recklessly disregarded the above misrepresentation (namely, that the Ong Trial was a robust clinical trial) based on each of their prior experiences with clinical trials and NDA submissions to the FDA.

95. On November 13, 2017, Defendants caused the Company to publish a press release announcing its financial and operational results for the third quarter of fiscal year 2017. In this press release, Defendant Schelling states in relevant part:

We became a public Nasdaq-listed company, closed a concurrent financing and *announced positive results from our pivotal clinical trial of EDSIVO™, each a critical step in bringing us closer to our goal of becoming a leading pharmaceutical company that acquires, develops and commercializes therapies for the treatment of patients with serious rare and ultra-rare diseases with critical unmet medical need We continue to successfully advance our lead product candidate, EDSIVO™, a potential life-saving therapy for patients with vEDS.* We believe that our current cash position will allow us to advance EDSIVO™ through NDA submission with the FDA in the first half of 2018. As a public company, we look forward to advancing and expanding our pipeline with the goal of bringing multiple products to patients over the next several years. [Emphasis added].

96. The November 2017 press release was false and misleading because the Ong Trial was not a “pivotal clinical trial” and the Company was not successfully advancing its lead product candidate, EDSIVO. In authorizing or otherwise supporting this press release, Defendants knew or recklessly disregarded the above misrepresentation (namely, that the Ong Trial was pivotal clinical trial which would successfully advance EDSIVO as a NDA candidate) based on each of their prior experiences with clinical trials and NDA submissions to the FDA.

97. On December 11, 2017, Defendants caused the Company to file a Prospectus Supplement with the SEC. The purpose of this Supplemental Prospectus was to raise capital to fund the Company’s efforts to bring EDSIVO to market. This Supplemental Prospectus also states:

In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, *the FDA agreed that additional clinical development is not needed* and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS. [Emphasis added].

98. This Prospectus Supplement was false and misleading because the FDA did not agree that additional clinical development is not needed for the approval of EDSIVO. In authorizing or otherwise supporting this language in the Supplemental Prospectus, the Director Defendants knew or recklessly disregarded the above misrepresentation (namely, that the FDA agreed that additional clinical development is not needed) based on each of their prior experiences

with clinical trials and NDA submissions to the FDA.

99. On March 7, 2018, Defendants caused the Company to file its 2017 Form 10-K which was signed by Defendants. Under the 2017 Form 10-K's "Rationale for EDSIVO™ Treatment in vEDS" section heading, Defendants heavily relied upon the methodology and results of the Ong Trial.

100. Additionally, under the 2017 Form 10-K's "Registration Plan" section heading for EDSIVO, Defendants touted their meeting with the FDA and indicated that the agency had sanctioned the Ong Trial as a sufficient source of data to support the EDSIVO NDA:

In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS. The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing.

[Emphasis added]

101. Additionally, according to the 2017 Form 10-K, the Company had consulted with the FDA regarding potential data gaps that could hinder the Company's EDSIVO NDA filing. According to the 2017 Form 10-K, Defendants had received additional guidance concerning these gaps. Specifically, the 2017 Form 10-K stated:

In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.

We plan to have a pre-NDA meeting, which may consist of one or more consults, with the FDA in the second quarter of 2018. Subsequently, we expect to submit the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS at the end of the first half of 2018.

102. Appended as exhibits to the 2017 Form 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein Defendants Schelling and Palmin certified that “[t]he [2017 Form 10-K] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934[,]” and that “[t]he information contained in the [2017 Form 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

103. The 2017 Form 10-K was false and misleading because (1) the Company now stated that “the FDA agreed that an additional clinical trial is not likely needed” and did not provide any explanation for this change in language from its earlier Prospectus Supplement (discussed herein); (2) the Ong Trial was not robust or sufficient to support Acer’s EDSIVO NDA application; (3) the FDA did not agree that an additional clinical trial is not likely needed; and (4) Director Defendants knew or recklessly disregarded the above misrepresentations based on each of their prior experiences with clinical trials and NDA submissions to the FDA.

104. On April 9, 2018, Defendants caused the Company to file its Notice of Annual Meeting of Shareholders to be held on May 14, 2018 on Form DEF 14A with the SEC (the “2018 Proxy Statement”). Accompanying the 2018 Proxy Statement was the Company’s 2017 Form 10-K. The 2018 Proxy Statement asked Plaintiffs and other Company shareholders to vote on: (1) election of directors, (2) approve the Company’s reincorporation in Delaware, and (3) approve the Company’s 2018 Stock Incentive Plan. The Audit Committee report was included in the 2018 Proxy Statement. Neither the Audit Committee Report or the 2018 Proxy Statement mentioned

EDVISO, vEDS, or disclosed any significant deficiencies or material weaknesses in the design or operation of internal controls that could adversely affect the Company's ability to record, process, summarize and report financial data, and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls.

105. The 2018 Proxy Statement was false and misleading because (1) although it represented that the Company maintains procedures regarding corporate governance and ethical conduct, its Code of Ethics was disregarded as evidenced by the false and misleading statements identified herein, (2) failed to disclose the weaknesses of the Ong Trial as discussed herein, (3) the FDA had not agreed that additional clinical trials would not be needed, and (4) the Director Defendants knew or recklessly disregarded the false and misleading statements or omissions based on each of their prior experiences with clinical trials and NDA submissions to the FDA.

106. On July 31, 2018, Defendants caused the Company to file a Prospectus Supplement with the SEC. The purpose of this Prospectus Supplement was to raise additional capital to fund the Company's efforts to bring EDSIVO to market. This Prospectus Supplement states:

In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS

In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.

In June 2018, we held a Type C meeting and a Type B (pre-NDA) meeting with the FDA. We expect to submit the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS early in the fourth quarter of 2018. We also intend to request priority review

for EDSIVOTM which, if granted, could result in a Prescription Drug User Fee Act (PDUFA) action date in the late second quarter 2019. Additionally, the manuscript for the Paris (AP-HP) vEDS patient registry data has been submitted and is currently under peer review, and if published, will be included in support of our NDA but is not rate-limiting to submission of the NDA. [Emphasis added].

107. The Prospectus Supplement was false and misleading because (1) the Company now stated that “the FDA agreed that an additional clinical trial is not likely needed” and did not provide any explanation for this change in language from its earlier Prospectus Supplement (discussed herein), (2) the FDA did not agree that an additional clinical trial is not likely needed, and (3) Director Defendants knew or recklessly disregarded the above misrepresentations based on each of their prior experiences with clinical trials and NDA submissions to the FDA.

108. On October 29, 2018, Defendants caused the Company to issue a press release announcing the Company’s submission of its NDA for EDSIVO to the FDA for the treatment of vEDS (the “October 2018 Press Release”). The October 2018 Press Release contained a statement by William Andrews (“Andrews”), M.D., FACP, Chief Medical Officer of the Company. Andrews’s statement acclaimed EDSIVO’s NDA as the culmination of the “extensive efforts” of, *inter alia*, the Company’s employees and clinical sites, and the Company’s continued work with the FDA as the FDA reviewed EDSIVO’s NDA. Specifically, the Andrews’ statement in the October 2018 Press Release stated:

Our NDA submission represents the culmination of extensive efforts of our employees, investigators, clinical trial sites, contract research organizations, caregivers and patients We now look forward to continuing to work with the FDA as they review our NDA, with hopes to make EDSIVOTM available as quickly as possible in the U.S. We are grateful to the vEDS patient and advocacy community for their continued involvement, support and feedback as we work together to advance EDSIVOTM, which has the potential to be a significant step forward in the care of patients with this devastating disease.

109. On December 26, 2018, Defendants caused the Company to issue a press release announcing the FDA’s acceptance of, and grant of priority review for, the EDSIVO NDA (the

“December 2018 Press Release”). The December 2018 Press Release boasted that the FDA’s grant of priority review for EDSIVO’s NDA indicated that EDSIVO “offer[ed] a significant improvement in treatment or provide[d] treatment where no satisfactory alternative therapy exists.”

110. The December 2018 Press Release also included a statement by Andrews, again acclaiming EDSIVO’s NDA, this time as the product of the Company’s “hard work, passion and complete dedication[,]” which the Company would continue to exert alongside the FDA as EDSIVO’s NDA was reviewed by the FDA. Specifically, Andrews’ statement in the December 2018 Press Release stated:

The acceptance of our NDA for EDSIVO™ is an important step in our efforts to help patients with vEDS, who suffer with a devastating disease that currently has no approved treatment We have had the honor of learning about the significant challenges of living with vEDS directly from patients and their families. This has in large part driven the hard work, passion and complete dedication that our small team has given to this effort, and we will continue to do so as the FDA reviews our NDA for EDSIVO™. We are excited about the possibility of making EDSIVO™ available in the U.S. for patients in the near future.

111. On March 7, 2019, Defendants caused the Company to file an Annual Report on Form 10-K with the SEC, announcing the Company’s financial and operating results for the fiscal year ended December 31, 2018 (the “2018 Form 10-K”), which was signed by each of the Defendants. Under the 2018 Form 10-K’s “Rationale for EDSIVO™ Treatment in vEDS” section heading, Defendants again heavily relied upon the methodology and results of the Ong Trial. Under the 2018 Form 10-K’s “Registration Plan” section heading for EDSIVO, Defendants touted the FDA’s acceptance of EDSIVO’s NDA for priority review, which purportedly meant that EDSIVO “offer[ed] a significant improvement in treatment or provide[d] treatment where no satisfactory alternative therapy exists.” Under the same section heading, Defendants touted “a manuscript for the Paris (AP-HP) vEDS patient registry data” that was “submitted for publication

in a top-tier cardiology journal” and currently under peer review. According to the 2018 Form 10-K, “[i]f published, [Defendants would] submit the manuscript to the FDA for review as part of our NDA and as supplemental data to the Ong trial.”

112. Finally, the 2018 Form 10-K touted the risk profile of its drug candidates:

Our product candidates are believed to present a comparatively de-risked profile, having one or more of a favorable safety profile, clinical proof-of-concept data, mechanistic differentiation, and an accelerated path for development, which may include utilizing expedited programs (such as Priority Review) established by the FDA and/or using the regulatory pathway established under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (“FFDCA”) that allows an applicant to rely at least in part on third-party data for approval, which may expedite the preparation, submission, and approval of a marketing application.

113. Appended as exhibits to the 2018 Form 10-K were signed SOX certifications wherein Defendants Schelling and Palmin certified that “[t]he [2018 10-K] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934[,]” and that “[t]he information contained in the [2018 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company.”

114. The 2018 Form 10-K was false and misleading because the Director Defendants knew or recklessly disregarded that the Ong Trial was inadequate and otherwise deficient (as discussed herein) to support approval of the Company’s EDVSIVO NDA application based on each of their prior experiences with clinical trials and NDA submissions to the FDA.

115. On April 12, 2019, Defendants caused the Company to file its Notice of Annual Meeting of Shareholders to be held on May 17, 2019 on Form DEF 14A with the SEC (the “2019 Proxy Statement”). Accompanying the 2019 Proxy Statement was the Company’s 2018 Form 10-K. The Audit Committee Report was included in the 2018 Proxy Statement. Neither the Audit Committee Report or the 2019 Proxy Statement mentioned EDVSIVO, vEDS, or disclosed any significant deficiencies or material weaknesses in the design or operation of internal controls that

could adversely affect the Company's ability to record, process, summarize and report financial data, and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls.

116. The 2019 Proxy Statement was false and misleading because (1) although it represented that the Company maintains procedures regarding corporate governance and ethical conduct, its Code of Ethics was disregarded as evidenced by the false and misleading statements identified herein, (2) failed to disclose the weaknesses of the Ong Trial as discussed herein, (3) the FDA had not agreed that additional clinical trials would not be needed, and (4) the Director Defendants knew or recklessly disregarded the false and misleading statements or omissions based on each of their prior experiences with clinical trials and NDA submissions to the FDA.

117. On April 15, 2019, the American College of Cardiology published the results from its long-term observational study to determine the long-term outcomes associated with vascular Ehlers-Danlos Syndrome (vEDS) in the Journal of the American College of Cardiology ("JACC"). This observational study describes outcomes in 144 COL3A1-positive vEDS patients clinically monitored and treated at the French National Referral Center for Rare Vascular Diseases between the years 2000 and 2017. On April 16, 2019, Defendants caused the Company to publish a press release discussing this long-term observational study. On May 14, 2019, Defendants caused the Company to issue a press release regarding its first quarter 2019 financial results and providing a corporate update again discussing this long-term observational study.

118. When issuing the April 16, 2019 and May 14, 2019 press releases, Defendants caused the Company to omit relevant information contained in the long-term observational study, namely:

It is difficult to formally assess this beneficial effect in the absence of a placebo-controlled prospective trial, because other confounders might have influenced this

observation. In that regard, it can be argued that there is still no study that definitively proves that celiprolol affects mortality or vascular events.

119. In addition to the reasons stated above, the statements referenced above were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that (1) the Company lacked sufficient data to support filing EDSIVO's NDA with the FDA for the treatment of vEDS; (2) the Ong Trial was an inadequate and ill-controlled clinical study by FDA standards, and was comprised of an insufficiently small group size to support EDSIVO's NDA; (3) consequently, the FDA would likely reject EDSIVO's NDA; and (4) as a result, the Company's public statements were materially false and misleading at all relevant times.

XII. THE TRUTH BEGINS TO EMERGE

120. On January 28, 2019, an article entitled "Why experts say Acer is unlikely to get FDA nod for vEDS drug" in *Pharmaceutical Technology*. That article states in relevant part:

Acer Therapeutics' Edsivo (celiprolol) is not expected to win approval from the US Food and Drug Administration (FDA) for vascular Ehlers-Danlos syndrome (vEDS), as the registrational trial was too small and not well-controlled, according to experts.

* * *

The study that the approval of Edsivo would be based on was not well-designed, with an overall small trial size, said vEDS expert Dr Harry Dietz, Co-director of the Medical Genetics Fellowship Training Programme and Professor of Paediatrics at The Johns Hopkins Hospital, Baltimore, Maryland, US.

Only 53 patients were enrolled in the trial, indicating recruitment was likely to have been challenging, said Dietz, pointing out the trial was almost half the size that was initially targeted.

* * *

Besides the low patient figures, the imbalance between the experimental and control arms in terms of patients with the COL3A1 mutation means the results are also insufficient for FDA approval, said Dr Dietz and Dr Grossfeld.

121. On June 25, 2019, Defendants caused the Company to issue a press release entitled “Acer Therapeutics Receives Complete Response Letter from U.S. FDA for use of EDSIVO™ (celiprolol) in vEDS Patients” (the “June 2019 Press Release”), disclosing that the FDA had rejected the Company’s NDA for EDSIVO. The June 2019 Press Release cited the need for an “adequate and well-controlled trial” evaluating EDSIVO’s effectiveness in reducing the risk of clinical events in patients with vEDS. Specifically, the June 2019 Press Release stated:

Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EDSIVO™ for the treatment of vascular Ehlers-Danlos syndrome (vEDS). *The CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS. Acer plans to request a meeting to discuss the FDA’s response.*

“We remain committed to working closely with the FDA to fully understand its response,” said Chris Schelling, CEO and Founder of Acer. “We expect to respond to the FDA in the third quarter of this year.” [Emphasis added].

122. That same day, *Reuters* published an article titled “FDA declines to approve Acer Therapeutics’ rare genetic disorder treatment” (the “*Reuters Article*”). In discussing the FDA’s rejection of the Company’s FDA, the *Reuters Article* noted, among other things, how “[t]he small group size” of the Ong Trial had “raised questions among experts about the adequacy of the trial results.”

123. Also, on June 25, 2019, the Marfan Foundation published an article entitled “The Marfan Foundation Statement on Celiprolol” which stated in relevant part:

The Marfan Foundation, as well as representatives of its Professional Advisory

Board, have reviewed the underlying studies of the drug and agree that celiprolol does not warrant designation as a sole approved drug for the treatment of people with vEDS (see background below). The Foundation recommends that registries of affected individuals with COL3A1 mutations be assembled quickly to facilitate informative clinical trials.

* * *

The consensus expressed at the international vascular Ehlers-Danlos syndrome meeting in Amsterdam in May 2018 emphasized the need for a large and well-controlled clinical trial of celiprolol in vEDS and the eagerness of the international medical community to assist in this effort.

124. Following this news, the Company's stock price fell \$15.16 per share, or 78.63%, to close at \$4.12 per share on June 25, 2019.

125. On July 5, 2019, the Company filed a Form 8-K with the SEC and issued a press release and announced a corporate restructuring initiative which included a reduction of approximately 60% of its full-time workforce of 48 employees (reduced to 19) and a halt of pre-commercial activities for EDSIVO™ in light of the Complete Response Letter ("CRL") received from the FDA regarding its NDA for EDSIVO.

126. On this news and on July 5, 2019, the Company's stock price fell from its opening of \$3.69 to close at \$3.41.

XIII. SUBSEQUENT EVENTS

127. On August 5, 2019, the Company filed a Form 8-K with the SEC disclosing that it hosted a conference call and webcast on July 31, 2019 to discuss a detailed update on each of its pipeline programs and attached its Pipeline Update Presentation. In this presentation, the Company acknowledged the CRL and stated that it is working to "... determine the optimal path forward." In this presentation, the Company listed the EDSIVO "CRL and Next Steps" as follows:

- Submit a Type A meeting request, to make sure we fully understand the FDA's thought process for the CRL;

- Depending on outcome, consider submission of a Formal Dispute Resolution Request (FDRR);
- Depending on Issues and outcomes, we may be able to resubmit our NDA, but no assurances;
- The entire process will likely take many months and possibly a year or more to reach final outcome; and
- We will provide updates as appropriate and may discontinue the process at any point where risk/benefit no longer justifies continued resources

128. On January 2, 2020, Defendants caused the Company to file a Form 8-K with the SEC (the “1/2/20 Form 8-K”), announcing it was appealing the FDA’s June 24, 2019 adverse CRL.

In the 1/2/20 Form 8-K, the Company stated:

On December 30, 2019, the Company submitted a Formal Dispute Resolution Request to the Office of New Drugs of the United States Food and Drug Administration (“FDA”), appealing the previously announced Complete Response Letter that the Company received from the FDA on June 24, 2019 regarding its New Drug Application for EDSIVO™ (celiprolol) for the treatment of vascular Ehlers-Danlos syndrome in patients with a confirmed type III collagen (COL3A1) mutation.

129. The 1/2/20 Form 8-K also attached a Corporate Presentation “. . . that will be available on the Investor Relations page of the Company’s website at <https://acertx.com/investor-relations> and will be used at investor and other meetings.” In this presentation, the Company listed the EDSIVO “CRL and Next Steps” as follows:

EDSIVO™: CRL and Next Steps

- Received CRL from FDA on June 24, 2019
 - The CRL stated it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS
- Submitted Formal Dispute Resolution Request (FDRR) to the Office of New Drugs (OND) in December 2019
 - Working with Hyman, Phelps, & McNamara (HPM) and other leading industry experts
- The entire process will likely take many months – possibly a year or more – to reach a final outcome
- Updates to be provided as appropriate and may discontinue the process at any point where risk/benefit no longer justifies continued resources



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130. On March 18, 2020, Defendants caused the Company to file a Form 8-K with the SEC (the “3/18/20 Form 8-K”) and attached a press release announcing the FDA’s denial of its appeal to the FDA’s June 24, 2019 adverse CRL. The press release states:

[T]he Office of New Drugs (OND) of the U.S. Food and Drug Administration (FDA) has denied Acer’s appeal of the Complete Response Letter (CRL) in relation to the New Drug Application (NDA) for EDSIVO™. In its Appeal Denied letter, the OND describes possible paths forward for Acer to explore that could provide the substantial evidence of effectiveness needed to support a potential resubmission of the EDSIVO™ NDA for the treatment of patients with vascular Ehlers-Danlos syndrome (vEDS) with a confirmed COL3A1 mutation.

“We appreciate the OND’s time and attention in thoughtfully considering this FDRR,” said Chris Schelling, CEO and Founder of Acer. “While neither resubmission nor the prospect of approval of the EDSIVO™ NDA is assured, we are evaluating our possible next steps with the goal of resubmission of the EDSIVO™ NDA.”

131. On June 16, 2020, the District Court in the Securities Class Action filed its Memorandum Opinion and Order (ECF 54) substantially denying the Motion to Dismiss filed by the Company and Defendants Schelling and Palmin.

132. On July 14, 2020, Defendants caused the Company to file a Form 8-K with the SEC (the “7/14/20 Form 8-K”) announcing that it had “. . . updated its Corporate Presentation that will be available on the Investor Relations page of the Company’s website at <https://acertx.com/investor-relations> and will be used at investor and other meetings.” This Corporate Presentation was updated to add a COVID 19 drug and also updated the Company’s discussion of EDSIVO:

EDSIVO™: Regulatory Timeline

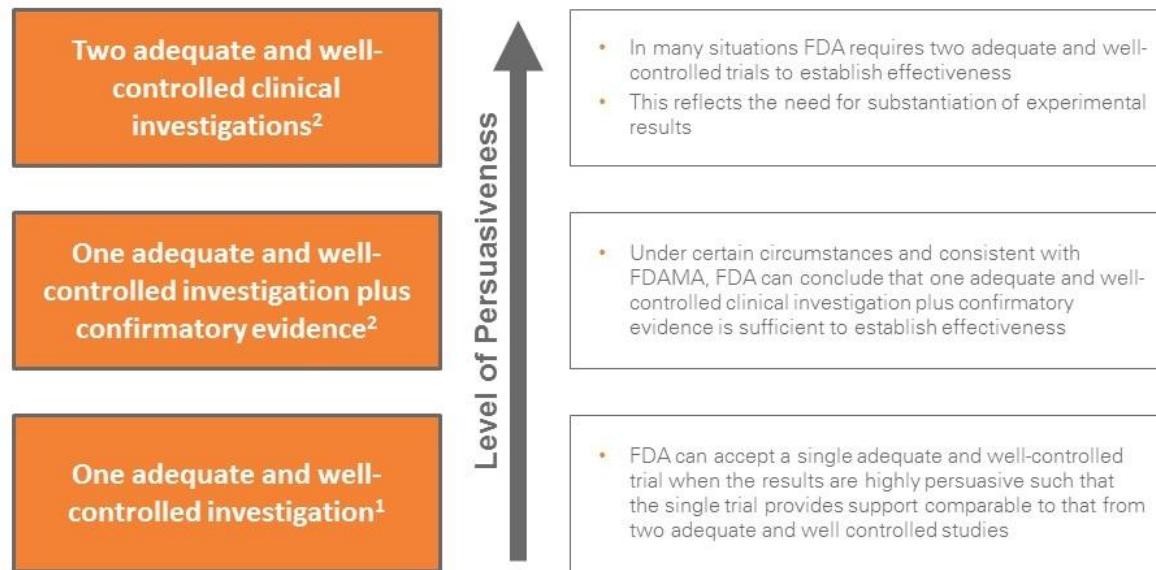
- **June 2019:** Received CRL from FDA
 - CRL stated it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS
- **December 2019:** Submitted Formal Dispute Resolution Request (FDRR) to the Office of New Drugs (OND)
- **March 2020:** Received OND FDRR response
 - Denied appeal of CRL
 - OND described possible paths forward for Acer to explore that could provide substantial evidence of effectiveness needed to support a potential resubmission of NDA
 - Evaluating possible next steps with the goal of EDSIVO™ NDA resubmission (neither resubmission nor approval is assured)
- Updates to be provided as appropriate and the company may discontinue the process at any point where risk/benefit no longer justifies continued resources



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FDA: Substantial Evidence of Effectiveness

THE QUANTITY OF CLINICAL EVIDENCE TO ESTABLISH EFFECTIVENESS



¹ FDA Guidance Document (1998) 'Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'.

² FDA Guidance Document (2019) 'Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products'.

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XIV. COURT'S MEMORANDUM OPINION AND ORDER IN THE SECURITIES CLASS ACTION

133. In the Securities Class Action, on June 16, 2020, Judge Gregory H. Wood issued a Memorandum Opinion and Order (ECF 43) ("Order") on the defendants' motion to dismiss the securities class action plaintiff's complaint. Below are excerpts from that Order:

Skiadas has plausibly alleged that Defendants' statements about what the FDA "agreed to" were false or misleading. In the 2017 Offering Documents, Defendants stated that "the FDA agreed" at a September 2015 meeting that "additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS." SAC ¶ 106. Similarly, in its 2017 Form 10-K, Defendants stated that "the FDA agreed" at the September 2015 meeting "that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS." *Id.* ¶ 108. And in the 2018 Offering Documents, Defendants repeated the statement from the 2017 Form 10-K. *Id.* ¶ 112.

The parties disagree about whether these statements were false or misleading because they disagree what these statements represent the FDA “agreed to.” Skiadas argues that a reasonable investor would have understood these statements to represent that the FDA agreed that no additional clinical development was necessary for the FDA to approve the EDSIVO NDA. Defendants argue that a reasonable investor would have understood these statements to concern only whether Acer could submit the EDSIVO NDA.

The challenged statements are ambiguous. Skiadas argues that the challenged statements are unqualified. Defendants stated that the FDA agreed that “an additional clinical trial is not likely needed[,]” full stop. And while the second clause of these sentences discuss submission, the first and second clauses are joined by the word “and.” That “and” does not unambiguously suggest a logical relationship between the two clauses. To see why “and” might be insufficient, imagine that allegedly false statements included a “so.” Then the above statement would have read that the FDA agreed “that an additional clinical trial is not likely needed and so stated that we may submit a 505(b)(2) NDA for EDSIVO.” That “so” would have signified that the second clause logically related to the first. Because the FDA agreed, Acer could submit its NDA. So, Skiadas argues, that the second clause of these sentences focuses on submission is largely irrelevant.²

Consider another example. Imagine that a friend tells you “John has arrived, and I need to go to the grocery store.” Does the fact that John has arrived tell you anything about your friend’s planned food-shopping trip? And conversely, does the fact that your friend needs to go to the grocery store tell you anything about John’s arrival? The answer to both questions is no. Your friend just chose to express two unrelated ideas in the same sentence. Skiadas argues that the same is true here.

Skiadas also argues that subsequent events bolster the argument that a reasonable investor would have interpreted Defendants’ statements as referring to EDSIVO approval, not submission. When the FDA issued its CRL stating that a clinical trial was necessary for EDSIVO approval, Acer’s stock price nosedived. *Id.* ¶ 11. Skiadas urges the Court to infer that investors expected the FDA to approve EDSIVO without another expensive clinical trial and that the Offering Documents contributed to this misimpression.

Yet Defendants argue that a reasonable investor would have understood the challenged statements as about NDA submission, not approval. Defendants lean heavily on the second half of these statements, both of which focus on submission. *See, e.g., id.* ¶ 108 (alleging that the FDA told Defendants “that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA

² “To be sure, the mere fact that a disclosure could be redrafted to be clearer does not itself render the initial statement ambiguous. Statements can almost always be redrafted to be clearer with the benefit of hindsight. The Court offers this example to illustrate that the first half of the challenged statement, as drafted, does not unambiguously refer to submission.”

for EDSIVO for the treatment of vEDS” (emphasis added)). As noted above, the second half of the sentence is not dispositive. But Defendants are correct that this context weighs in favor of construing the statements to be about submission, not approval.

Because the challenged statements are ambiguous, the Court cannot dismiss Skiadas’ claims based on those statements as a matter of law. At the motion to dismiss stage of a securities fraud action, “the court reads ambiguities” in challenged statements “in [the plaintiff’s] favor.” *Umbach v. Carrington Inv. Partners*, No. 3:08CV484 (EBB), 2009 WL 413346, at *6 (D. Conn. Feb. 18, 2009). That is simply an application of the maxim that a court must draw all reasonable inferences in the plaintiff’s favor on a motion to dismiss. Defendants’ statements were ambiguous, so the Court must construe them as referring to EDSIVO approval, not submission, at this stage.

Construing the challenged statements to be about EDSIVO approval—as the Court must—Skiadas has plausibly alleged that the statements were false or misleading. Skiadas alleges that the FDA did not, in fact, agree that no further clinical development was necessary before it would approve EDSIVO. And the FDA rejected Acer’s NDA in a CRL and noted that Acer would need to conduct a well-designed clinical trial before it would consider approving EDSIVO. The FDA’s statement in the CRL makes plausible the allegation that the FDA never agreed that no further clinical development was necessary before it would approve EDSIVO. So Skiadas has satisfied his burden to plead that Defendants’ statements about what the FDA “agreed to” were false or misleading.

Skiadas also alleges that Defendants’ statements in their 2017 Form 10-K and 2018 Offering Documents that the “FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing” was false or misleading. SAC ¶¶ 110, 114. Skiadas alleges that these statements were false or misleading because they “led investors to believe that the Ong Trial data were sufficient to support FDA approval.” *Id.* ¶¶ 111, 115. But that is not so. No reasonable investor could interpret the statement that the FDA “provided . . . guidance on the expected presentation of existing clinical data” to mean that the FDA had indicated that the Ong Trial data were adequate to assure FDA approval of EDSIVO. And Skiadas has alleged no facts to suggest that the FDA did not provide Acer “guidance” on its expected presentation. That the FDA ultimately rejected the Acer’s NDA for EDSIVO Skiadas does not suggest that the FDA did not provide Acer with guidance about how to present existing data. Skiadas has thus failed to allege that the statements were false or misleading.

See Order at pp. 15-18.

XV. DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

134. Plaintiffs bring this action derivatively in the right and for the benefit of the

Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties and gross mismanagement by Defendants.

135. Plaintiffs will adequately and fairly represent the interests of the Company and its shareholders in enforcing and prosecuting its rights and have retained counsel competent and experienced in derivative litigation.

136. Plaintiffs are current owners of Acer stock. Plaintiffs understands their obligation to hold stock throughout the duration of this action and are prepared to do so.

137. During the wrongful course of conduct at the Company, the Board consisted of the Director Defendants. Because of the facts set forth throughout this Amended Complaint, demand on the Board to institute this action is not necessary because such a demand would have been a futile and useless act.

138. The Acer Board is currently comprised of Defendants Aselage, Schelling, Griffin, Dunn and Amello. Thus, Plaintiffs are required to show that a majority of the Demand Defendants, *i.e.*, three (3), cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action.

139. The Director Defendants face a substantial likelihood of liability in this action because they caused the Company to issue false and misleading statements concerning its future prospects. Because of their advisory, executive, managerial, and directorial positions with the Company, each of the Director Defendants had knowledge of material non-public information regarding the Company and was directly involved in the operations of the Company at the highest levels.

140. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith

effort to prevent or remedy that situation.

141. The Director Defendants (or at the very least a majority of them) cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this complaint, Plaintiffs have not made (and should be excused from making) a pre-filing demand on the Board to initiate this action because making a demand would be a futile and useless act.

142. The Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

143. The Director Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

144. Because of their participation in the gross dereliction of fiduciary duties, and breaches of the duties of due care, good faith, and loyalty, Director Defendants are unable to comply with their fiduciary duties and prosecute this action.

145. Additionally, each of the Director Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the Company.

A. Defendant Schelling

146. Defendant Schelling is not disinterested or independent, and therefore, is incapable

of considering demand because Defendant Schelling (as CEO of the Company) is an employee of the Company who derives substantially all of his income from his employment with the Company, making him not independent. From 2017 through 2019, Defendant Schelling received compensation from the Company in the amount of \$2,602,669, consisting of salary, bonus, and option awards, and during a period when the Company was generating no revenue. As such, Defendant Schelling cannot independently consider any demand to sue himself for breaching his fiduciary duties to the Company, because that would expose him to liability and threaten his livelihood.

147. This lack of independence and financial benefits received by Defendant Schelling renders him incapable of impartially considering a demand to commence and vigorously prosecute this action.

148. In addition, Defendant Schelling is a defendant in the Securities Class Action and faces significant liability as Defendants' motion to dismiss in that action has been denied and the case is proceeding.

149. As such, Defendant Schelling cannot independently consider any demand to sue himself for breaching his fiduciary duties to the Company, because that would expose him to liability and threaten his livelihood.

B. Defendants Griffin, Amello and Dunn

150. Defendants Griffin, Amello, and Dunn are members of the Company's Audit Committee.

151. Pursuant to the Company's Audit Committee Charter, the members of the Audit Committee are responsible for, *inter alia*, inquiring of and reviewing "any disclosures made to the Committee by the Company's chief executive officer and chief financial officer (or persons

performing such functions) during their certification process for the Company's Form 10-K and Forms 10-Q as to the existence of any significant deficiencies or material weaknesses in the design or operation of internal controls that could adversely affect the Company's ability to record, process, summarize and report financial data, and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls."

152. Defendants Griffin, Amello, and Dunn, and during the times each served on this committee, breached their fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failed to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. Therefore, Defendants Griffin, Amello, and Dunn face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile.

C. Defendants Aselage, Schelling, Griffin, Dunn and Amello

153. Defendants Aselage, Schelling, Griffin, Dunn and Amello each have a history working for other pharmaceutical companies which companies pursued clinical trials and drug approvals with the FDA. With this prior experience, each of them knew or recklessly disregarded NDA requirements, including but not limited to, clinical trial requirements. Defendants Aselage, Schelling, Griffin, Dunn and Amello ignored their prior experience and permitted the false and misleading statements as alleged herein.

154. In violation of the Company's Code of Ethics, Defendants Aselage, Schelling, Griffin, Dunn and Amello conducted little, if any, oversight of the Company's internal controls over public reporting and disclosures, and of the Company's scheme to perpetuate the false and misleading statements to the public regarding EDSIVO receiving FDA approval as set forth herein.

155. Additionally, during this time, Defendants Aselage, Schelling, Griffin, Dunn and Amello were excessively compensated while the Company was generating no revenue.

D. Defendants Aselage, Schelling, Griffin, Dunn and Amello

156. Defendants Aselage, Schelling, Griffin, Dunn and Amello each signed the false and misleading 2017 Form 10-K, which falsely represented Defendants' statements about what the FDA "agreed to" that were false and/or misleading. For example, in its 2017 Form 10-K, Defendants stated that "the FDA agreed" at the September 2015 meeting "that an additional clinical trial is not likely needed and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS." The 2017 Form 10-K was found to contain false and misleading statements for pleading purposes in the Securities Class Action. See, e.g., Judge Gregory Woods Memorandum Opinion and Order (ECF 54) in the Securities Class Action at p. 20 ("Any competent speaker of the English language could tell you that a statement that something is "not needed" is different from a statement that it is "not likely needed." Defendants' decision to alter the wording of their public statements suggests that the first statement was inaccurate.")

XVI. DAMAGE TO THE COMPANY

157. Defendants' faithless acts and omissions, breaches of fiduciary duty and violations of the federal securities laws and state law have severely damaged and will continue to damage the Company. By engaging in the aforementioned unlawful scheme, Defendants: (1) caused the Company to issue materially false and misleading statements to its shareholders and the investment community; (2) caused the Company common stock to trade at artificially inflated prices, exposing the Company to millions of dollars in potential civil, regulatory and criminal liability to investors and regulators, including the SEC; and (3) exposed the Company to tens of millions of dollars in legal fees to investigate this misconduct and to defend the Company in the Securities Class Action.

158. Moreover, these actions have irreparably damaged the Company's goodwill and reputation. For at least the foreseeable future, the Company will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that the Company's ability to raise equity capital or debt on favorable terms in the future is now impaired.

XVII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Against Director Defendants For Breach Of Fiduciary Duties)

159. Plaintiffs incorporate by reference and re-allege each and every allegation contained above, as though fully set forth herein.

160. Defendants owe the Company fiduciary obligations. By reason of their fiduciary relationships, Defendants owed and owe the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

161. Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

162. Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. In breach of their fiduciary duties owed to the Company, Defendants failed to disclose that: (1) the Company lacked sufficient data to support filing EDSIVO's NDA with the FDA for the treatment of vEDS; (2) the Ong Trial was an inadequate and ill-controlled clinical study by FDA standards, and was comprised of an insufficiently small group size to support EDSIVO's NDA; (3) consequently, the FDA would likely reject EDSIVO's NDA; and (4) as a result, the Company's public statements were materially false and misleading at all relevant times.

163. Defendants had actual knowledge of the above misrepresentations and omissions

of material facts set forth herein, or acted with reckless disregard for the truth, in that they failed to ascertain and to disclose such facts, even though such facts were available to them.

164. As a direct and proximate result of Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, Defendants are liable to the Company.

165. As a direct and proximate result of Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending securities lawsuits, severe damage to the share price of the Company, resulting in an increased cost of capital, the waste of corporate assets, and reputational harm.

SECOND CAUSE OF ACTION

(Against Defendants For Unjust Enrichment)

166. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

167. As a result of the conduct described above, Defendants have been unjustly enriched at the expense of the Company.

168. Further, Defendants received tens of thousands of dollars in cash bonuses and equity incentive compensation by causing the Company to issue materially false and misleading statements to the investment community that exposed it to millions of dollars in potential liability to investors and regulators. Defendants should be required to disgorge the gains which they obtained and/or will otherwise unjustly obtain at the expense of the Company. A constructive trust for the benefit of the Company should be imposed thereon.

169. All the stock sales proceeds and cash bonus and equity compensation payments

provided to Defendants were at the expense of the Company. The Company received no benefit from these stock sales proceeds and payments. The Company was damaged by such stock sales proceeds and payments.

170. Plaintiffs, as shareholders and representatives of the Company, seek restitution from Defendants, and seek an order of this Court disgorging all profits, benefits, and other compensation obtained by Defendants, as a result of their wrongful conduct and fiduciary breaches.

THIRD CAUSE OF ACTION

(Against Defendants For Abuse Of Control)

171. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

172. Defendants breached their fiduciary duties which allowed them to abuse their ability to control and influence the Company.

173. As a direct and proximate result of Defendants' actions, the Company sustained significant damages. As a result of the misconduct alleged herein, Defendants are liable to the Company.

FOURTH CAUSE OF ACTION

(Against Defendants For Waste Of Corporate Assets)

174. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

175. As a result of the foregoing, and by failing to properly consider the interests of the Company and its shareholders, Defendants have caused the Company to waste valuable corporate assets, to incur many millions of dollars of legal liability and costs to defend unlawful actions, to

engage in internal investigations, and to lose financing from investors and business from future customers who no longer trust the Company.

176. As a result of the waste of corporate assets, Defendants are each liable to the Company.

FIFTH CAUSE OF ACTION

(Against Defendants For Indemnification And Contribution)

177. Plaintiffs incorporate by reference and re-allege each and every allegation contained above, as though fully set forth herein.

178. The misconduct of Defendants described above has exposed the Company to significant liability under various federal and state laws.

179. The Company is alleged to be liable to private persons, entities, and/or classes by virtue of many of the same facts alleged herein.

180. Defendants have caused the Company to suffer substantial harm through their misconduct.

181. The Company is entitled to contribution and indemnification from Defendants in connection with all such claims that have been, are, or may be asserted against the Company by virtue of Defendants' misconduct.

SIXTH CAUSE OF ACTION

(Against Defendants For Violations Of Section 14(a) Of The Exchange Act)

182. Plaintiffs incorporate by reference and re-allege each and every allegation set forth above, as though fully set forth herein.

183. The Section 14(a) Exchange Act claims alleged herein are based solely on negligence. They are not based on any allegation of reckless or knowing conduct by or on behalf

of Defendants. The Section 14(a) claims alleged herein do not allege and do not sound in fraud. Plaintiffs specifically disclaims any allegations of, reliance upon any allegation of, or reference to any allegation of fraud, scienter, or recklessness with regard to these nonfraud claims.

184. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that “[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 78I of this title.”

185. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. §240.14a-9.

186. In the exercise of reasonable care, Defendants should have known that by misrepresenting or failing to disclose the foregoing material facts, the statements contained in the 2018 Proxy Statement were materially false and misleading as those statements pertain to the Company’s 2018 Stock Incentive Plan. Proposal 4 of the Proxy states:

PROPOSAL 4

APPROVAL OF THE 2018 STOCK INCENTIVE PLAN

We are asking our shareholders to approve our 2018 Stock Incentive Plan (the “2018 Plan”) at the Annual Meeting. On March 1, 2018, the Board approved the 2018 Plan, subject to shareholder approval. If this Proposal 4 is approved and the 2018 Plan becomes effective, no further grants will be made under the Amended

and Restated 2010 Stock Incentive Plan (the “2010 Plan”) and the 2013 Stock Incentive Plan, as amended (the “2013 Plan”), of Private Acer which we assumed in the merger on September 19, 2017. All outstanding stock awards granted under the 2010 Plan and the 2013 Plan will continue to be subject to the terms and conditions as set forth in the agreements evidencing such stock awards and the terms of the 2010 Plan or the 2013 Plan, as applicable.

If our shareholders approve the 2018 Plan, the total number of shares of our common stock reserved for issuance under the 2018 Plan will initially consist of (i) 500,000 shares plus (ii) the number of shares subject to outstanding awards under the 2010 Plan and the 2013 Plan that are forfeited or terminate prior to exercise or settlement and would otherwise be returned to the share reserve under the 2010 Plan or the 2013 Plan, as applicable, plus the number of shares subject to vesting restrictions under the 2010 Plan or the 2013 Plan that are subsequently forfeited, plus any reserved shares not issued or subject to outstanding grants, up to a maximum of 635,170 shares. In addition, the number of shares that have been authorized for issuance under the 2018 Plan will be automatically increased on the first day of each fiscal year beginning on January 1, 2019 and ending on (and including) January 1, 2028, in an amount equal to the lesser of (i) 4% of the outstanding shares of our common stock on the last day of the immediately preceding fiscal year, or (ii) another amount (including zero) determined by our Board of Directors (“Board”).

Why You Should Vote for Approval of our 2018 Stock Incentive Plan

Equity Awards Are an Important Part of Our Compensation Philosophy

The 2018 Plan is critical to our ongoing effort to build shareholder value. Equity incentive awards are central to our compensation program. Our Compensation Committee and Board believe that our ability to grant equity incentives to new and existing employees has helped us attract, retain and motivate key talent. For example, since the potential value of stock options is realized only if our share price increases, this form of compensation provides a strong incentive for employees to work to grow the business and build shareholder value, and is most attractive to employees who share the entrepreneurial spirit that we believe is key to making our company a success.

The 2018 Plan will also provide us with continued flexibility in designing equity incentives in an environment where a number of companies have moved from traditional option grants to other stock awards, including restricted stock awards, stock appreciation rights, restricted stock unit awards, performance stock awards and performance cash awards. Accordingly, the 2018 Plan will allow us to utilize a broad array of equity incentives in order to secure and retain the services.

Our 2010 Plan is Running Low on Shares and our 2013 Plan Share Reserve has been Depleted

Grants of equity awards to our employees, consultants, executive officers and directors are currently made only from the 2010 Plan. All available shares under the 2013 Plan are currently subject to outstanding awards and no further awards may be made thereunder. After carefully forecasting, we anticipate that the 2010 Plan will not have any remaining shares in its share reserve by the end of the second quarter of 2018, and we will not be able to issue equity to our employees, consultants, executive officers and directors unless our shareholders approve a new stock plan. While we could increase cash compensation if we are unable to grant equity incentives, we anticipate that we will have difficulty attracting, retaining, and motivating our employees, consultants, executive officers and directors if we are unable to make equity grants to them. Stock incentive awards are a more effective executive compensation vehicle than cash at a growth-oriented, entrepreneurial company because they deliver high potential value with a smaller impact on current income and cash flow. Therefore, we are asking our shareholders to approve the 2018 Plan

187. The misrepresentations and omissions were material to Plaintiffs in voting on the matter as to whether to approve the Company's 2018 Stock Incentive Plan set forth for stockholder determination in the 2018 Proxy Statement, including but not limited to, the election of directors.

188. The Company was damaged as a result of Defendants material misrepresentations and omissions in the 2018 Proxy Statement.

XVIII. REQUEST FOR RELIEF

WHEREFORE, Plaintiffs demand judgment as follows:

A. Determining that this action is a proper derivative action maintainable under law, and that demand is excused;

B. Awarding, against all Defendants and in favor of the Company, the damages sustained by the Company as a result of Defendants' breaches of their fiduciary duties;

C. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its stockholders from a repeat of the damaging events described herein, including, but not limited to:

1. a proposal to strengthen the Company's internal controls;
2. a proposal to strengthen the Company's communications and disclosures;
3. a proposal to strengthen the Company's oversight of its disclosure procedures; and
4. a proposal to strengthen the Company's controls over financial reporting;

D. Awarding to Plaintiffs the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

XIX. JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: July 22, 2020

O'KELLY & ERNST, LLC

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